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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/224,781 01/04/99 LIBIN

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JAMES V COSTIGAN
HEDMAN GIBSON & COSTIGAN
1185 AVENUE OF THE AMERICAS
NEW YORK NY 10036

HM12/0719

EXAMINER

ROSE, S

ART UNIT

PAPER NUMBER

1614

4

DATE MAILED:

07/19/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/22471

Applicant(s)

L1B/N

Examiner

S182P 12058

Group Art Unit

1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 2, 3 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 3 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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It is the policy of the USPTO to give pending patent claims their broadest reasonable interpretation as patent application claims.

Applicant Barry Libin has five (5) claims, recently allowed, on March 23, 1999, filed November 5, 1998, in (I) copending application Serial No. 09/186,825, filed November 5, 1998, drawn to the methods of treating mucositis in an immunocompromised patient by contacting the affected disease sites with (a) Triclosan "(T)"; in claim 2, in a liquid formulation with a solubilizer; in claim 3, in a semi-solid formulation; in claim 5, with a fluoride; and in claim 4, the composition consists essentially of Triclosan "(T)". In claims 1-3 and 5, the methods are "open-ended", and the claims recite "comprising". The scope of the affected disease sites of the "mucositis" encompassed by these five claims includes all of the mucus membranes of the body, (topical, nasal, eyes, vaginal, rectal, etc.), as well as the oral cavity.

There are other pending applications by Barry Libin that differ from these five claims of 09/186,825, (as noted above), only in obvious features known in the art, raising the issue of obviousness-type double patenting, (and/or overlap in scope), which may (or might) be moot upon the filing of a terminal disclaimer. The difference from the five claims of 09/186,825, is that they also include (b) a cationic antimicrobial, one which

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has been described in the prior art with (I) with (T) Triclosan, and by themselves for treating such mucositis, herpetic or fungus infected patients affected sites.

Barry Libin (II) (U.S. Patent No. 5,855,872) which issued January 5, 1999, and application 08/934,327, filed September 19, 1997) has seven claims to methods for treating diseased tissues resulting from a herpes simplex infection giving rise to inflammation of the tissues and lesions comprising contacting said inflammation with a composition consisting essentially of (a) Triclosan (T), (b) a cationic antimicrobial and (c) a solubilizer(s) for the Triclosan. In claims 2 and 3 the (b) is cetylpyridinium chloride (CPC) or chlorhexidine (CHX), respectively. In claims 4, 5 and 6, the composition is a topically applied ointment, oil/water emulsion, or both with petrolatum.

The scope of the patent claims encompasses mucositis oral, topical, head, body, groin, buttock, superficial skin and mucus membrane.

In (III) 09/167,225, filed October 6, 1998) (no parent), with eight (8) claims, Triclosan, and a cationic antibacterial agent, not necessarily CPC as in claim 3, and which can be chlorhexidine (claim 2), are applied to the affected disease sites of mucositis, not necessarily oral mucositis, in a composition which is not necessarily a semi-solid, as in claim 5,

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but can be a liquid, in claim 3. In claims 7 and 8, a fluoride is included. Claim 8 is a composition of (a) Triclosan, (b) cationic antibacterial agent, and (c) a fluoride to inhibit tooth decay.

In (IV) 09/224,781 filed January 4, 1999 (no parent), with 30 claims, Triclosan, or Triclosan and another antimicrobial agent, not necessarily a cationic antimicrobial agent, not necessarily CPC (claim 10), and which can be chlorhexidine (claim 9) are applied to the affected areas, not necessarily oral mucositis (it can be dermal), in a composition which is not necessarily a semi-solid (claims 4, 12, 16 and 22), but can be a liquid (claims 3, 11, 21 and 24), and in claims 6, 7 and 14 to treat mucositis, herpetic, or fungal infections.

Both 09/167,225 and 09/224,781 are subject to obviousness-type double patenting grounds of rejection on the allowed claims of 09/186,825, filed November 5, 1998, allowed March 23, 1999, claiming methods of treating mucositis, fungus or herpetic infections with Triclosan and with Triclosan and cationic antibacterial agents.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 09/186,825 in view of abstracted prior art cited on the PTO-892, describing encompassed species of cationic antimicrobial agents as in the Markush group of claims 9, 19, 27, like chlorhexidine, to treat encompassed mucositis, fungus or herpetic virus infected sites in immunocompromised patients, and an encompassed species of liquid and semi-solid carrier, and in further view of Libin (U.S. 5,855,872), wherein diseased tissues can be treated with both agents.

Triclosan alone meets claims 1-7, 15-17 and 23-25, as in the allowed claims of 09/186,825 raising questions of overlap in scope.

This is a provisional obviousness-type double patenting rejection.

Serial No. 09/224,781

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Shep Rose
Senior Primary Examiner
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SKR:cdc
July 8, 1999

**SHEP K. ROSE
PRIMARY EXAMINER
GROUP 1200**